



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

**MEMORANDUM**

**DATE:** August 20, 2019

**SUBJECT:** Efficacy review for NP 4.5 (D & F) Detergent/Disinfectant, EPA Reg. No. 1839-95 (DP Barcode: 452497; E-sub: 39135)

**FROM:** César E. Cordero  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P) *César E. Cordero*

**THRU:** Thao Pham, Acting Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) *Thao Pham*  
Date Signed: September 5, 2019

**TO:** Eric Miederhoff, Team 31 / Joseph Daniels  
Regulatory Management Branch  
Antimicrobials Division (7510P)

**APPLICANT:** STEPAN COMPANY  
22 West Frontage Road  
Northfield, IL 60093

**FORMULATION FROM LABEL:**

<b><u>Active Ingredient(s)</u></b>	<b><u>% by wt.</u></b>
Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chlorides .....	2.25%
Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	
dimethyl ethylbenzyl ammonium chlorides .....	2.25%
<b><u>Other ingredients:</u></b> .....	<b><u>95.50%</u></b>
Total.....	100.00%

## I BACKGROUND

**Product Description (as packaged, as applied):** Liquid concentrate

**Submission type:** Label amendment,

**Currently registered efficacy claim(s):** Broad spectrum disinfectant (hard non-porous; non-food contact surfaces): Virucidal, bactericidal, fungicidal; Mildewstat; Cleaner and deodorizer.

**Requested action(s):** Review efficacy study to support addition of Hepatitis A Virus (HAV) to the virucidal claims.

### **Documents considered in this review:**

- Cover letter from applicant/agent to EPA dated December 14, 2018
- Data Matrix (EPA Form 8570-35) dated December 10, 2018
- Proposed label dated 05/03/19
- 1 Efficacy study (MRID 50845701)
- Confidential Statement of Formula (EPA Form 4670-4) dated 08/28/13

## II PROPOSED DIRECTIONS FOR USE

(For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:)

(This product or product name) is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

or

This product is not for use on critical and semi-critical medical device surfaces.

**DISINFECTION** - To disinfect inanimate, hard, non-porous surfaces add 2 ounces of (this product or product name) per gallon of water. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid.

For heavily soiled areas, a pre-cleaning step is required.

(Note: one of the following statements must appear after the dilution use directions)

**BACTERICIDAL STABILITY of USE-DILUTION:** Efficacy tests confirm that (this product or product name) when diluted as directed remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* for (up to 7 days) (up to 1 week) (up to 14 days) (up to two weeks) (up to 21 days) (up to 3 weeks) (up to one month) (up to 30 days) (up to 4 weeks) when stored in a sealed container such as a spray bottle. If the (use-dilution) (use-solution) (diluted product) becomes visibly dirty or contaminated, it must be discarded and fresh (use-dilution) (use-solution) (diluted product) must be prepared. Always use clean, properly labeled containers when diluting (this product or product name). Bactericidal stability of the (use-dilution) (use-solution) (diluted product) does not apply to open containers such as buckets or pails.

(or)

Prepare a fresh (use-dilution) (use-solution) daily or more often if the (use-dilution) (use-solution) becomes visibly dirty or diluted.

(or)

Prepare a fresh solution for each use.

**PACKETS** (*for pre-measured tear open packets*) – (Simply) (tear) open and pour contents into 1 gallon of water. Keep packets in box until ready to use.

or

Pour contents of (2 oz) packet into 1 gallon of water. Keep packets in box until ready to use.

**To disinfect toilet bowls:** flush toilet, add 2 ounces of (this product or product name) directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

**Non-Acid Toilet Bowl Disinfection/Cleaner Directions:** Remove gross filth prior to disinfection.

**From concentrate:** Add 2 ounces per gallon to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

**From use-solution:** Empty toilet bowl or urinal and apply 2 ounces per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, brush or swab thoroughly and allow to stand for 10 minutes and flush.

**For heavy duty use:** Empty toilet bowl or urinal and apply 8 ounces per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, brush or swab thoroughly and allow to stand for 10 minutes and flush.

**To disinfect food processing premises:** Before using this product, food products and packaging materials must be removed from the area or carefully protected. For floors, walls, and storage areas, add 2 ounces of (this product or product name) per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. After use, all surfaces in the area must be thoroughly rinsed with potable water.

**To disinfect food service establishment food contact surfaces:** Before using this product, food products and packaging materials must be removed from the area or carefully protected. For countertops, appliances, tables, add 2 ounces of (this product or product name) per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

**BACTERICIDAL ACTIVITY** - When diluted at the rate of 2 ounces per gallon of water, (this product or product name) exhibits effective, one-step disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella enterica*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Staphylococcus aureus*,

Methicillin resistant *Staphylococcus aureus* (MRSA), Vancomycin intermediate resistant *Staphylococcus aureus* (VISA), *Streptococcus pyogenes* (Clinical-Flesh Eating Strain BIRD M3) and *Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem Resistant, *Acinetobacter baumannii*, *Enterococcus faecium*, Vancomycin resistant *Enterococcus faecalis* (VRE) and meets all requirements for hospital use.

**FUNGICIDAL ACTIVITY** - At the 2 ounces per gallon dilution, (this product or product name) is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (causative agent of Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet. Follow the Disinfection directions.

**\*VIRUCIDAL ACTIVITY** – (This product or product name), when used on environmental, inanimate, hard, non-porous surfaces at 2 ounces per gallon of water, exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Adenovirus Type 2 (causative agent of upper respiratory infections), Vaccinia virus (representative of the Pox virus group), Human Coronavirus (ATCC VR-740, Strain 229E), Human Immunodeficiency Virus Type I (HIV-1), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Norovirus (Norwalk Virus), Bovine Viral Diarrhea Virus (BVDV), Feline calicivirus (FCV), SARS Associated Coronavirus, Porcine Respiratory & Reproductive Syndrome Virus (PRRSV) (Strain NVSL) and Avian Influenza A. Follow the Disinfection directions.

At 8 ounces per gallon or equivalent dilution rate (2812 ppm (mg/L) active quat), this product (product name) is effective against the following viruses on hard non-porous environmental surface with a 10 minute contact time: Canine Parvovirus (CPV), Canine Adenovirus (causative agent of Infectious Canine Hepatitis), Canine Coronavirus (causative agent of Canine Coronavirus Disease, Canine Gastroenteritis), Canine Parainfluenza Virus (causative agent of viral Kennel Cough), Feline Panleukopenia (Feline Parvovirus), Feline Rhinotracheitis (causative agent of Feline Herpes virus Infection), Feline Coronavirus (causative agent of Feline Infectious Peritonitis), Feline Picornavirus and Porcine Parvovirus.

**Canine Parvovirus (CPV) Activity:** At 8 ounces per gallon of water or equivalent dilution (2812 ppm (mg/l) active quat), this product (product name) inactivates Canine Parvovirus (CPV) on hard, non-porous, environmental surfaces in the presence of 5% blood serum with a 10 minute contact time.

**Hepatitis A (HAV) Activity:** At 10 ounces per gallon of water or equivalent dilution, this product (product name) inactivates Hepatitis A (HAV) on hard, non-porous, environmental surfaces in the presence of 5% blood serum with a 10 minute contact time.

**KILLS HIV-1, HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (this product or product name).

**CONTACT TIME:** Allow surface to remain wet for 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).**

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces, add 2 ounces of (this product or product name) per gallon of water. Apply solution with a cloth, mop, sponge, hand pump trigger sprayer or low pressure coarse sprayer making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

**To Control Mold and Mildew on Large, Inflatable, Non-Porous Plastic and Rubber Structures (animals, promotional items, moonwalk, slides, obstacle course play equipment, exercise equipment, and wrestling mats):** Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 8 ounces of this product (product name) per 4 gallons of water (2 ounces per gallon of water) (703 ppm active quaternary) (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not use equipment until treatment has been absorbed, set or dried.

**GENERAL CLEANING** – Apply (this product or product name) to soiled area with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer. (This product or product name) can be diluted at 2 ounces per gallon or applied at full strength. Thoroughly wet soiled surface and scrub as necessary.

**DEODORIZATION** - To deodorize, apply (this product or product name) as indicated under the heading DISINFECTION.

**Cleaning/Deodorizing Directions:**

Add 1 to 2 ounces per gallon of water to clean and deodorize windows, mirrors and glass surfaces.

**Use a coarse spray device.** Spray 6-8 inches from surface, rub with sponge or cloth. Do not breathe spray mist.

**POULTRY (AND SWINE) PREMISE DISINFECTION**

**Site Preparation:** The first step in any on-going sanitation program must be the removal of gross contamination and debris. This is accomplished by using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal

cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, thoroughly clean all surfaces with soap or detergent and rinse with water.

**Cleaning And Disinfection:** For all general cleaning and disinfection use 2 ounces of (this product or product name) per gallon of water. Apply (this product or product name) using a cloth, mop, hand pump trigger sprayer or low pressure coarse sprayer so as to thoroughly wet surface to be disinfected. Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution after each use.

## **APPLICATIONS AND USE DILUTION**

**Poultry (And Swine) Premise Disinfection (Special Instructions for Inactivating Avian Influenza A):** Remove all (poultry) (swine) (animals) and feeds from premises, trucks, cars, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by (poultry) (swine) (animals). Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 2 ounces of (this product or product name) per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house (poultry) (swine) (animals) or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. Immerse all halters, ropes, and other types of equipment used in handling and restraining (poultry) (swine) (animals), as well as forks, shovels, and scrapers used for removing litter and manure.

**Hatcheries:** Use 2 ounces of (this product or product name) per gallon of water to treat the following hard non-porous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more. Rinse with potable water before reuse. Then allow to air dry. For heavily soiled areas, a pre-cleaning step is required.

**Vehicles:** Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and (this product or product name). Use 2 ounces per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

**Shoe Bath Directions:** Shoe baths containing one inch of freshly made solution must be placed at all entrances to buildings, hatcheries and at all the entrances to the production and packaging rooms. Scrape waterproof shoes and place in 2 ounces of (this product or product name) per gallon of water solution for 10 minutes prior to entering area. Change the use-solution in the bath daily or sooner if solution appears dirty.

**Dressing Plant Use:** Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution, 2 ounces of (this product or product name) per gallon of water. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water.

**Veterinary Practice/Animal Care/Animal Laboratory/Zoos/Pet Shop/Kennels Disinfection Directions:** For cleaning and disinfecting the following hard non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc.

Remove all litter, droppings and manure from floors, walls and surfaces occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 ounces of (this product or product name) per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

**Farm Premise Use:** Do not use in milking stalls, milking parlors or milk houses. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 2 ounces of (this product or product name) per gallon of water (or equivalent dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

**Ultrasonic Bath Disinfectant Directions:** Use (this product or product name) to disinfect hard non-porous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh solution at 2 ounces of (this product or product name) per gallon of water directly into bath chamber. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

**Disinfection of Hard Non-Porous Surfaces in Whirlpool Units:** After using the whirlpool unit, drain and refill with fresh water to just cover the intake valve. Add 2 ounces of (this product or product name) for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair, lift and any/all related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly cleaned, drain the solution from the unit and rinse any/all cleaned surfaces with fresh water. Repeat for heavy soiled units.

**Commercial Florist Use Directions:** To clean, disinfect and deodorize hard non-porous surfaces in one step, prepare use-solution by adding (mixing) 2 ounces per gallon of water. For heavy-duty use, add (mix) 8 ounces per gallon of water.

Remove all leaves, petals, garbage and refuse. Pre-clean surfaces using pressurized water where possible. Apply use- solution to hard (inanimate) non-porous surfaces thoroughly wetting surfaces as recommended and required, with a cloth, mop, brush, sponge or sprayer.

For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse mist pump or trigger sprayer. Spray 6-8 inches from surface; rub with brush, sponge or cloth. Do not breathe spray mist.

Treated surfaces must remain wet for 10 minutes. Allow to air dry.

Prepare a fresh solution at least daily or sooner if use-solution becomes visibly dirty.

**Disinfection of Barber/Salon Tools Directions:** Immerse pre-cleaned barber/salon tools (combs, brushes, razors, manicure/pedicure tools, clippers, scissors, trimmer blades) in a 2 ounces of this product (product name) per gallon of water use-solution (or equivalent dilution) (703 ppm active quaternary) for at least 10 minutes. Rinse instruments thoroughly and dry before reuse. A fresh use-solution must be prepared daily or more often if the use-solution becomes cloudy or soiled.

**NOTE:** Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean non-contaminated receptacle. Prolonged immersion may cause damage to stainless steel or metal instruments.

### III STUDY SUMMARIES

<b>1.</b>	<b>MRID</b>	<b>50845701</b>	<b>Study Completion Date:</b>	04/22/2019			
<b>Study Objective</b>		Disinfectant – Virucidal (Additional)					
<b>Testing Lab; Lab Study ID</b>		Microbac Laboratories; Project Number 123-500					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Hepatitis A Virus (Strain HM175/18F, University of Ottawa)					
<b>Indicator Cell Culture</b>		FRhK-4, University of Ottawa					
<b>Test Method</b>		Virucidal Hard-Surface Efficacy Test (Microbac Protocol # 123.2.02.14.19)					
<b>Application Method</b>		Liquid					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	NP 4.5 (D&F) Detergent/Disinfectant					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	5037-029-001 and 5037-029-002					
	<b>Preparation</b>	Tested concentration: LCL Dilution: 10 oz. per gal. (1 ml of concentrate product in 11.8 mL of diluent) Diluent: Sterile deionized water					
<b>Soil load</b>		5% serum in viral inoculum					
<b>Carrier type, # per lot</b>		1 glass petri dish carrier per lot					
<b>Test conditions</b>		<b>Contact time</b>	10 min.	<b>Temp</b>	20°C	<b>RH</b>	29%
<b>Neutralizer</b>		DMEM, 10% FBS, 2% HEPES, 0.5% Lecithin, 0.5% Poly-80, 0.025N HCl					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, etc.)		<p>No protocol amendments or deviations were reported in this study.</p> <p>Hepatitis A Virus is a small non-enveloped virus.</p> <p>Two batches; tested at LCL</p> <p>Reported incubation time of 16-21 days. Typical incubation time for this virus is 6-7 days.</p>					



#### IV STUDY RESULTS

##### Disinfection – Virucidal Efficacy

<i>10 minutes contact time, 5% Soil Load; Diluted 10 oz. per Gallon in Sterile Deionized Water</i>						
MRID	Organism	Dilutions	Results		Plate Recovery Control Titer (Log <sub>10</sub> TCID <sub>50</sub> /mL)	Log <sub>10</sub> Reduction
			Lot 5037-029-001	Lot 5037-029-002		
50845701	Hepatitis A Virus (Strain HM175/18F, University of Ottawa)	10 <sup>-2</sup> to 10 <sup>-3</sup> dilution	Cytotoxicity	Cytotoxicity	6.75	≥3.25
		10 <sup>-4</sup> to 10 <sup>-7</sup> dilution	0/4	0/4		
		Log <sub>10</sub> TCID <sub>50</sub> /mL	≤3.50	≤3.50		

## II CONCLUSION

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50845701	Disinfectant – Additional, virucidal	Hard non-porous surface	Liquid concentrate 10 oz. per gal.	10 minutes	5% serum in viral inoculum	Sterile deionized water	• Hepatitis A Virus (Strain HM175/18F, University of Ottawa)	Yes

## VI LABEL COMMENTS

Label Date: 05/03/19 (Label attached)

1. The proposed label claims that the product, NP 4.5 (D & F) Detergent/Disinfectant, when diluted 10 ounces of product per gallon of water, or equivalent dilution, is an effective disinfectant against Hepatitis A Virus (HAV), on hard, non-porous, environmental surfaces in the presence of 5% blood serum with a 10-minutes contact time:

- *Hepatitis A Virus* (Strain HM175/18F, University of Ottawa)

These claims are **partially acceptable**. As testing was conducted using sterile deionized water, label directions should specify dilution using sterile deionized water. To support claims for “dilute with water” consult OCSP Guideline 810.2000 for details about testing using hard water.

2. Make the following changes to the proposed label:

- a. **Throughout the label:**

- i. Since testing under MRID 49644001 for basal disinfectant claims was conducted using sterile deionized water, specify throughout all the disinfection use directions/instructions that the product should be diluted using “sterile deionized water” or submit efficacy data to support hard water dilution.
- ii. Replace the words “gross”, “heavy, and “heavily” for “visible/visibly” when used as a descriptor of “contaminated” areas and/or “filth”. This descriptor, though still subjective, provides an observable indicator to the user that we believe would provide more consistency in the way the use directions are applied, when compared to heavily/gross and similar descriptors.
- iii. Throughout the label, qualify all “virucide” and “virucidal” claims with the viruses tested.
- iv. Qualify all claims that combine cleaning and disinfection (e.g. “one-step disinfectant cleaner”, disinfectant cleaner, clean and disinfect”, etc.) with the following, or similar language: “when used according to disinfection directions”.

- b. **Page 3 of 17:**

- i. Remove or revise “This product (product name) meets AOAC Use-Dilution Test Standards for hospital disinfectants” as this claim is misleading. The AOAC UDM is a test method, not a performance standard. An appropriate alternative is “This product was tested according to the AOAC Use Dilution Method.”

- c. **Page 5 of 17:**

- i. Remove “household” from the claim “Kills household bacteria”. The agency has not identified a “household” strain of bacteria.
- ii. Remove “one step cleaner” as this is misleading. One-step claims are reserved for disinfection and sanitization claims.

d. **Page 6 and 7 of 17:**

- i. Add a qualifier to the “**MICRO-ORGANISMS**” table for those organisms that deviate from the common use dilution of 2 oz per gallon (e.g. 8 or 10 oz per gallon – Hepatitis A Virus). Alternatively, consider adding a column to the table that includes the corresponding use dilution against each of the organisms. This may be useful for the end users and potentially reduce misuse and/or improper application of the product.

e. **Page 7 and 8 of 17:**

- i. Add qualifier (e.g. footnote) to the “**DISINFECTION**” and “**VIRUCIDAL ACTIVITY**” sections to clarify that some of the organisms may require a more concentrated use dilution to achieve disinfection. Alternatively, the registrant can state this use dilution difference and direct the user to the specific “use directions” for such organisms (e.g. Canine Parvovirus (CPV) Activity and Hepatitis A (HAV) Activity). This may be useful for the end users and potentially reduce misuse and/or improper application of the product.
- ii. Revise “*Trichophyton mentagrophytes*” to “*Trichophyton interdigitale*” as the ATCC designation has changed. Acceptable to qualify with “formerly *Trichophyton mentagrophytes*”.

# NP 4.5 (D&F) Detergent/Disinfectant

## Front Panel

### ACTIVE INGREDIENTS

Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chlorides .....	2.25%
Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	
dimethyl ethylbenzyl ammonium chlorides .....	2.25%
<b>INERT INGREDIENTS</b> .....	<b>95.50%</b>
Total .....	100.00%

**NET CONTENTS(:)**    XXX (oz)(ounces)(gallon(s))(gal(s))

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

### FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

**If swallowed:** Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**(OPTIONAL)(Hotline Number)** You may contact xxx/xxx-xxxx for emergency medical treatment information.

### NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

See (side) (back) panel for additional precautionary statements.

## FRONT, BACK OR SIDE PANEL

EPA REG. NO. 1839-95

EPA EST. NO. 1839-IL-01

### STEPAN COMPANY

22 West Frontage Road

Northfield, IL 60093

## **MARKETING CLAIMS**

- DISINFECTANT
- CLEANER
- ONE-STEP DISINFECTANT CLEANER
- DETERGENT
- BACTERICIDE
- \*VIRUCIDE
- FUNGICIDE (against pathogenic fungi)
- MILDEWSTAT (on hard non-porous, inanimate surfaces)
- DEODORIZER
- Effective in the presence of 5% serum contamination
- For Home, Hospital, Institutional and Industrial Use
- For Farm, School, Restaurant, Food Handling and Processing Areas, Equine, Poultry/Turkey Farm, Bar, Tavern and Institutional Kitchen Use
- Formulated for Effective Farm Premise Disinfection
- Formulated for Effective Poultry Premise Disinfection
- Formulated for Effective Swine Premise Disinfection
- Formulated for Effective Veterinary Practice/Animal Care/Animal Laboratory Disinfection
- KILLS GERMS
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)
- Kills Carbapenem Resistant Enterobacteriaceae (CRE)\*\*
- Kills (Hepatitis A Virus (HAV)), (Hepatitis B Virus (HBV)), (Hepatitis C Virus (HC))
- Kills ESKAPE Pathogen Group\*\*\*

\*\**Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem Resistant

\*\*\* Vancomycin Resistant *Enterococcus faecalis* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA), *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, *Enterobacter aerogenes*

- Cost Effective and Time Efficient when used with (the) (refillable spray bottle)(mechanical spray device) (cordless)(backpack) (sprayer) (low pressure sprayer)(trigger sprayer)(handheld mechanical sprayer) (applicator/sprayer name).
- This product is (designed)(formulated) for use with (refillable spray bottle)(mechanical spray device) (cordless)(backpack)(handheld)(sprayer)(low pressure sprayer)(trigger sprayer)(handheld mechanical sprayer)(applicator/sprayer name).
- (Refer to (applicator)(sprayer)(equipment)(user) manual for (additional)(specific) operation instruction before use.
- Refer to the *insert applicator/sprayer name* -and/or- user manual -or- safety data sheet (SDS) for (more information)(any additional PPE).
- *This claim can only be used if product is currently in the EPA L list:* Product (Product name) can be found on EPA list L: 'Registered antimicrobial products that meet CDC criteria for use against the EBOLA virus. < insert link for the latest EPA List or [https://www.epa.gov/sites/production/files/2018-01/documents/2018.10.01.listl\\_.pdf](https://www.epa.gov/sites/production/files/2018-01/documents/2018.10.01.listl_.pdf)>

NP 4.5 (D&F) Detergent/Disinfectant is a phosphate free formulation designed to provide effective cleaning, deodorization, and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments, transportation terminals, automotive garages, office buildings, manufacturing facilities, lodging establishments, retail businesses, athletic/recreational facilities, sports stadiums, amphitheaters, convention centers, and households where housekeeping is of prime importance in controlling the hazard of cross contamination.

NP 4.5 (D&F) Detergent/Disinfectant (this product or product name) for use in:

- Hospitals, nursing homes, medical and dental offices and clinics, operating rooms, isolation wards, and medical research facilities.
- Patient care rooms and facilities, recovery, anesthesia, emergency rooms, X-ray CAT labs, newborn nurseries, orthopedics, whirlpools, footbaths, respiratory therapy.
- EMS and fire facilities.
- Day care centers and nurseries, sick rooms.
- Acute care institutions, alternate care institutions, home healthcare institutions.
- Life care retirement communities.
- Restaurants and bars, cafeterias, pizzerias, taverns, cocktail lounges, institutional kitchens, fast food operations food establishments, coffee shops, donut shops, bagel stores, liquor stores and food storage areas.

- Supermarkets, convenience stores, retail and wholesale establishments, department stores, shopping malls, gift shops, video stores, bookstores, photocopy centers, bicycle shops, auto repair centers, toy stores, dressing rooms and laundries.
- Crime scenes and funeral homes, mortuaries, burial vaults, mausoleums, autopsy rooms.
- Police stations, courthouses, municipal government buildings, prisons, jails.
- Institutional facilities, laboratories, factories, manufacturing facilities, business and office buildings, restrooms, hotels and motels and transportation terminals.
- Institutional kitchens and bathrooms.
- Institutions, schools and colleges, universities, education institutions, school administration offices, churches, classrooms, athletic facilities, sports stadiums, convention centers and locker rooms
- Camp grounds, play grounds, and recreational facilities, sports areas, sport complexes, sport stadiums.
- Food processing plants, hog farms, poultry and turkey farms and egg processing plants.
- Veterinary clinics, animal life science laboratories, kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, and other animal care facilities.
- Automotive garages, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis and airplanes.
- Cruise lines, airline terminals, shipping terminals, bus stations, train stations, airports, heliport transportation terminals.
- Health clubs, spas, tanning spas (salons), massage/facial salons, hair/nail/pedicure salons, barber/beauty shops, tattoo parlors.
- Museums, art galleries, post offices, performance/theatre centers, banks, libraries, movie houses.
- Recycling centers and equipment.
- Commercial florist and flower shops.
- Kitchen, bathrooms, and other household areas.
- Basements, cellars, bedrooms, attics, living rooms, porches, garages.

(This product or product name) is a one step detergent disinfectant that is effective against a broad spectrum of bacteria, is virucidal\* (including HIV-1, HBV and HCV) and inhibits the growth of mold and mildew and their odors when used as directed.

This product has demonstrated virucidal efficacy against Hepatitis B (HBV), Hepatitis C (HCV) and Human Immunodeficiency Virus (HIV-1) on hard inanimate, environmental surfaces.

[This product has demonstrated virucidal efficacy against \[insert claim from Virucidal Activity Table \(pg. 7\)\] on hard inanimate, environmental surfaces.](#)

This product (product name) meets AOAC Use-Dilution Test Standards for hospital disinfectants.

This product (product name) can be used as a disinfectant on hard, non-porous, environmental surfaces (at 703 ppm active).

When used as directed, this product (product name) is a concentrated hospital use disinfectant that is an effective broad spectrum bactericide and virucide\*.

(This product or product name), when used as directed, is formulated to disinfect the following hard non-porous inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, vanity tops, shower stalls, bathtubs, and cabinets.

- Non-food contact glass, metal, stainless steel, glazed porcelain, glazed ceramic, sealed granite, sealed marble, plastic, chrome and vinyl.
- Tables, chairs, desks, bed frames, walls, cabinets, doorknobs and garbage cans.
- Non-wooden picnic tables and outdoor furniture (except cushions and wood frames).
- Telephones.
- Non-food contact counter tops, sinks, refrigerator exteriors, coolers, freezer exteriors, stovetops, appliances, non-food contact equipment, shelves, racks and carts.
- Shower stalls, shower doors, vinyl and plastic shower curtains, tubs and glazed tiles, toilets, urinals, porcelain tile and restroom fixtures.
- Kennels and cages.
- Windows and mirrors.

- For larger areas such as operating rooms and patient care facilities, (this product or product name) is designed to provide both general cleaning and disinfecting.
- Large inflatable non-porous plastic (rubber) (advertising) structures: animals, promotional items, moonwalks, slides, obstacle course play equipment, exercise equipment, exercise mats, wrestling mats.

(This product or product name) deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls, and other areas which are prone to odors caused by microorganisms.

(This product or product name) is a no rinse disinfectant cleaner that disinfects, cleans and deodorizes in one labor saving step.

When used as directed, (this product or product name) will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.

(This product or product name) cleans, shines, deodorizes and disinfects all hard non-porous surfaces listed on the label. It inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and fresh smelling.

(This product or product name) is for non-scratch cleaning of showers and tubs, shower doors, vinyl and plastic shower curtains, fixtures and toilet bowls.

(This product or product name) is for use in institutional kitchens and bathrooms.

Use (this product or product name) to clean and disinfect non-porous personal protective safety equipment, protective headgear, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs. Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water (about 120°F), and allow to air dry. (Caution: Cleaning at the 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.)

(This product or product name) is a multi-surface cleaner, deodorizer and disinfectant. Use on windows, mirrors, and other non-food contact glass surfaces.

This product (product name) is a versatile disinfectant for veterinarian and animal care.

This product (product name) is a versatile cleaner and broad spectrum disinfectant formulated for use on bath and therapy equipment (whirlpools).

This product (product name) is a versatile broad spectrum disinfectant formulated for use in Ultrasonic Baths.

Use this product (product name) to disinfect non-porous salon/barber tools and instruments: combs, brushes, scissors, blades, and manicure instruments.

This product (product name) has been formulated to aid in the reduction of cross-contamination on treated surfaces not only in hospitals, but in schools, institutions and industry.

(This product or product name) is an effective antimicrobial cleaner designed for use by wholesale and retail florists, shippers and greenhouses.

When used as directed, (this product or product name) will disinfect hard, non-porous surfaces such as flower buckets, floors and walls of coolers, design and packing benches and counter tops.

(This product or product name) may be relied on to deodorize coolers, buckets, garbage pails and other areas where obnoxious odors may develop.

Use (this product or product name) to clean, disinfect and deodorize flower buckets, walls and floors of coolers, shippers, greenhouse packing areas, garbage pails and other areas where obnoxious odors may develop.

(This product or product name) may be used as a general purpose antimicrobial detergent in florist shops, wholesale florist, shippers, greenhouse packing areas and other commercial floriculture places for efficient cleaning and antimicrobial action against certain bacteria which cause:

1. Plugging of stems with slime, which reduces uptake of water for various flowers including roses, chrysanthemums, gladioli and tulips.
2. Production of ethylene gas, which may injure blooms of the various sensitive flowers including carnations, snapdragons, some orchids, babies breath, sweet peas, freesia and alstroemeria.

(This product or product name) is for Poultry Premise Disinfection (Hatcheries):

Egg Receiving Area	Tray Dumping Area	Chick Processing Area
Egg Holding Area	Chick Holding Area	Chick Loading Area
Setter Room	Hatchery Room	Poultry Buildings

(This product or product name) is for Swine Premise Disinfection:

Farrowing Barns and Areas	Dressing Plants	Blocks
Waterers and Feeders	Loading Equipment	Creep Area
Hauling Equipment	Nursery	Chutes

When used as directed, (this product or product name) is formulated to disinfect hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, vinyl, chrome, bathrooms, shower stalls, shower doors, bathtubs, toilets, bathroom fixtures, kitchens, countertops, sinks, exteriors of (microwaves, refrigerators, stoves, and other) kitchen appliances, stovetops, automobile



interiors, cabinets, tables, chairs, desks, dining room surfaces, doorknobs, garbage cans, telephones, hospital beds, traction devices, MRI, CAT, examining tables, scales, paddles, wheelchairs, ultrasonic baths and whirlpools. For larger areas: operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

(This product or product name) deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls, behind and under sinks and other areas where bacterial growth can cause malodors.

(This product or product name) cleans, deodorizes and disinfects all hard non-porous household surfaces. It inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and fresh smelling.

(This product or product name) is a non-abrasive (non-scratch) cleaner for showers, tubs, shower doors, vinyl and plastic shower curtains, fixtures and toilet bowls.

(This product or product name) is an economical concentrate that can be used with a mop and bucket, hand pump trigger sprayer, low pressure coarse sprayer or sponge.

This product (product name) neutralizes on contact musty odors and tough odors from smoke, pet accidents, and spills.

This product (product name) is formulated to effectively eliminate offensive odors caused by mold and mildew.

This product (product name) (controls) (reduces) (eliminates) (destroys) odors to make your home (kitchen) (bathroom) sanitary.

This product (product name) is effective against household odors by animal waste, septic tank or sewage backup, smoke and bathroom and kitchen odors.

This product (product name) may be used in work areas such as tool rooms and garages for odor control and light duty cleaning.

Disinfects kitchen (bathroom) surfaces. Kill germs. Kills household bacteria.

Kills Athlete's Foot fungus on bathroom surfaces.

Kills common kitchen (bathroom) germs (and viruses).

This product (product name) controls (reduces) (eliminates) (neutralizes) (destroys) odors to make your home (kitchen) (bathroom) sanitary.

This product (product name) may be used in work areas such as garages for odor control and light duty cleaning.

Cleans everyday kitchen messes (surfaces).

Great for use (on) (in) the (kitchen), (bathroom), (floors) and other household areas. Remove (eliminates) odors. Deodorizes.

Eliminates odors caused by bacteria (and) (mildew) (and) (non-fresh foods). Kills odor causing bacteria in the kitchen (bathroom).

This product (product name) is an economical concentrate that can be used with a mop and bucket, hand pump trigger sprayer, low pressure coarse sprayer or sponge.

Floor cleaner.

One step cleaner.

Cleans and shines.

This product contains no phosphorous.

## **SURFACES & USE SITES**

*Note to Reviewer: Product label may include a graphic depiction of surfaces or sites listed on the EPA-approved master label.*

### **Hard, non-porous surfaces:**

Appliance Exteriors	Full Face Breathing Apparatus <sup>1</sup>	Remote Controls
Airplanes	Garbage(cans)(pails)	Restroom Fixtures
(Bath)tubs	Gas Masks <sup>1</sup>	Restrooms
Bathrooms	Glass	Salad Bar Sneeze Guards 2
Bed Frames	Glazed Ceramic Tile	Scissors
Bidets	Glazed Porcelain	Sealed Granite
Bins	Goggles <sup>1</sup>	Sealed Marble
Brush(es)	Half Mask Respirators <sup>1</sup>	Shelves
Busses	Hard hats <sup>1</sup>	Shower (doors)(curtains)

Cabinets	Inflatable Advertising Structures	Shower Stalls
Cages	Inflatable play structures	Sinks (Basins)
Cars	Kennels	Sports Equipment
Carts	Kitchens 2	Stainless Steel <sup>3</sup>
Chairs	Laminate	Stovetops 2
Chrome	Light Switches	Tables 2
Clipper(s)	Litter Boxes	Trains
Comb(s)	Metal <sup>3</sup>	Telephones
Coolers	Metal Blinds <sup>3</sup>	Toilets
Desks	Microwave (oven) exteriors	Tools
Diaper Pails	Mirrors	Trimmer Blade(s)
Doorknobs (and pulls)	Non-wood Furniture	Urinals
Counters (Countertops) 2	Outdoor Patio Furniture	Vanity Tops
Drinking Fountains	Patient Chairs <sup>3</sup>	Vinyl
Ear Muffs <sup>1</sup>	Plastic	(Washable) Walls
Exercise Equipment	Plastic Laundry Baskets	Wheelchairs <sup>3</sup>
Exercise Mats	Plastic Mattress Covers	Whirlpool Interiors
Face Shields <sup>1</sup>	Racks	Windows
Faucets	Razor(s)	Wrestling Mats
Floors	Recycling Bins	(Barber)(Salon) tools
Freezer Exteriors	Refrigerator Exteriors	

<sup>1</sup> Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water (about 120°F), and allow to air dry. (Caution: Cleaning at the 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.)

<sup>2</sup> Non-food contact use site(s) where surfaces may contact with food. Refer to direction for use under subtitle "To disinfect food processing premises" and/or "To disinfect food service establishment food contact surfaces".

<sup>3</sup> [This product (or product) is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.] or [This product (or product) is not for use on critical and semi-critical medical device surfaces.]

## **MICRO-ORGANISMS**

This product has been tested and found to be efficacious against the following micro-organisms on hard, non-porous surfaces:

ORGANISM	ATCC No.
<b>Bactericidal Activity:</b>	
Brevibacterium ammoniagenes	6871
Enterobacter aerogenes	13048
Escherichia coli	11229
Klebsiella pneumoniae	4352
Methicillin resistant Staphylococcus aureus (MRSA)	33593
Pseudomonas aeruginosa	15442
Salmonella enterica	10708
Salmonella schottmuelleri	8759
Shigella dysenteriae	12180
Staphylococcus aureus	6538
Streptococcus faecalis	10541
Streptococcus pyogenes (Clinical - Flesh Eating Strain BIRD M3)	
Streptococcus salivarius	9222
Vancomycin intermediate resistant Staphylococcus aureus (VISA)	
Klebsiella pneumoniae New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem Resistant	
Acinetobacter baumannii	19606

Enterococcus faecium	19434
Vancomycin resistant Enterococcus faecalis (VRE)	51299
<b>Virucidal Activity:</b>	
Adenovirus Type 2	
Avian Influenza A Virus (H3N2) (Avian Reassortant)	VR-2072
Avian Influenza Virus Type A (Turkey/WIS/66) (H9N2)	
Bovine Viral Diarrhea Virus (BVDV)	
Feline Calicivirus (FCV)	
Hepatitis A virus (HAV)	
Hepatitis B virus (HBV)	
Hepatitis C virus (HCV)	
Herpes Simplex Type 1	
Human Coronavirus	VR-740
Human Immunodeficiency Virus Type 1 (HIV-1)	
Influenza A <sub>2</sub> /Japan	
Norovirus (Norwalk Virus)	
Pandemic 2009 H1N1 Influenza A Virus	
Porcine Respiratory & Reproductive Syndrome Virus (PRRSV)	
SARS Associated Coronavirus	
Vaccinia Virus	
Canine Parvovirus	
Canine Adenovirus	
Canine Coronavirus	
Canine Parainfluenza Virus	
Feline Panleukopenia	
Feline Rhinotracheitis	
Feline Coronavirus	
Feline Picornavirus	
Porcine Parvovirus	
<b>Fungicidal Activity:</b>	
Trichophyton mentagrophytes	9533
<b>Mildewstat Activity:</b>	
Aspergillus niger	6275

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

*(For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:)*

(This product or product name) is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

or

This product is not for use on critical and semi-critical medical device surfaces.

**DISINFECTION** - To disinfect inanimate, hard, non-porous surfaces add 2 ounces of (this product or product name) per gallon of water. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. For heavily soiled areas, a pre-cleaning step is required.

**(Note: one of the following statements must appear after the dilution use directions)**

**BACTERICIDAL STABILITY of USE-DILUTION:** Efficacy tests confirm that (this product or product name) when diluted as directed remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* for (up to 7 days) (up to 1 week) (up to 14 days) (up to two weeks) (up to 21 days) (up to 3 weeks) (up to one month) (up to 30 days) (up to 4 weeks) when stored in a sealed container such as a spray bottle. If the (use-dilution) (use-solution) (diluted product) becomes visibly dirty or contaminated, it must be discarded and fresh (use-dilution) (use-solution) (diluted product) must be prepared. Always use clean, properly labeled containers when diluting (this product or product name). Bactericidal stability of the (use-dilution) (use-solution) (diluted product) does not apply to open containers such as buckets or pails.

(or)

Prepare a fresh (use-dilution) (use-solution) daily or more often if the (use-dilution) (use-solution) becomes visibly dirty or diluted.

(or)

Prepare a fresh solution for each use.

**PACKETS** (for pre-measured tear open packets) – (Simply) (tear) open and pour contents into 1 gallon of water. Keep packets in box until ready to use.

or

Pour contents of (2 oz) packet into 1 gallon of water. Keep packets in box until ready to use.

**To disinfect toilet bowls:** flush toilet, add 2 ounces of (this product or product name) directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

**Non-Acid Toilet Bowl Disinfection/Cleaner Directions:** Remove gross filth prior to disinfection.

**From concentrate:** Add 2 ounces per gallon to the toilet bowl and mix. Brush thoroughly over exposed surfaces and under the rim, allow to stand for 10 minutes and flush.

**From use-solution:** Empty toilet bowl or urinal and apply 2 ounces per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, brush or swab thoroughly and allow to stand for 10 minutes and flush.

**For heavy duty use:** Empty toilet bowl or urinal and apply 8 ounces per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, brush or swab thoroughly and allow to stand for 10 minutes and flush.

**To disinfect food processing premises:** Before using this product, food products and packaging materials must be removed from the area or carefully protected. For floors, walls, and storage areas, add 2 ounces of (this product or product name) per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid. After use, all surfaces in the area must be thoroughly rinsed with potable water.

**To disinfect food service establishment food contact surfaces:** Before using this product, food products and packaging materials must be removed from the area or carefully protected. For countertops, appliances, tables, add 2 ounces of (this product or product name) per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

**BACTERICIDAL ACTIVITY** - When diluted at the rate of 2 ounces per gallon of water, (this product or product name) exhibits effective, one-step disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella enterica*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Staphylococcus aureus*, Methicillin resistant *Staphylococcus aureus* (MRSA), Vancomycin intermediate resistant *Staphylococcus aureus* (VISA), *Streptococcus pyogenes* (Clinical-Flesh Eating Strain BIRD M3) and *Klebsiella pneumoniae* New Delhi Metallo-Beta Lactamase (NDM-1) Carbapenem Resistant, *Acinetobacter baumannii*, *Enterococcus faecium*, Vancomycin resistant *Enterococcus faecalis* (VRE) and meets all requirements for hospital use.

**FUNGICIDAL ACTIVITY** - At the 2 ounces per gallon dilution, (this product or product name) is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (causative agent of Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet. Follow the Disinfection directions.

**\*VIRUCIDAL ACTIVITY** – (This product or product name), when used on environmental, inanimate, hard, non-porous surfaces at 2 ounces per gallon of water, exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Adenovirus Type 2 (causative agent of upper respiratory infections), Vaccinia virus (representative of the Pox virus group), Human Coronavirus (ATCC VR-740, Strain 229E), Human Immunodeficiency Virus Type I (HIV-1), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Norovirus (Norwalk Virus), Bovine Viral Diarrhea Virus (BVDV), Feline calicivirus (FCV), SARS Associated Coronavirus, Porcine Respiratory & Reproductive Syndrome Virus (PRRSV) (Strain NVSL) and Avian Influenza A. Follow the Disinfection directions.

*(optional statements to appear anywhere on the label)*

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

- This product (Product Name) has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product (Product Name) has demonstrated effectiveness against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.

At 8 ounces per gallon or equivalent dilution rate (2812 ppm (mg/L) active quat), this product (product name) is effective against the following viruses on hard non-porous environmental surface with a 10 minute contact time: Canine Parvovirus (CPV), Canine Adenovirus (causative agent of Infectious Canine Hepatitis), Canine Coronavirus (causative agent of Canine Coronavirus Disease, Canine Gastroenteritis), Canine Parainfluenza Virus (causative agent of viral Kennel Cough), Feline Panleukopenia (Feline Parvovirus), Feline Rhinotracheitis (causative agent of Feline Herpes virus Infection), Feline Coronavirus (causative agent of Feline Infectious Peritonitis), Feline Picornavirus and Porcine Parvovirus.

**Canine Parvovirus (CPV) Activity:** At 8 ounces per gallon of water or equivalent dilution (2812 ppm (mg/l) active quat), this product (product name) inactivates Canine Parvovirus (CPV) on hard, non-porous, environmental surfaces in the presence of 5% blood serum with a 10 minute contact time.

**Hepatitis A (HAV) Activity:** At 10 ounces per gallon of water or equivalent dilution, this product (product name) inactivates Hepatitis A (HAV) on hard, non-porous, environmental surfaces in the presence of 5% blood serum with a 10 minute contact time.

**KILLS HIV-1, HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

#### **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings.

**CLEANING PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (this product or product name).

**CONTACT TIME:** Allow surface to remain wet for 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).**

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces, add 2 ounces of (this product or product name) per gallon of water. Apply solution with a cloth, mop, sponge, hand pump trigger sprayer or low pressure coarse sprayer making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears.

**To Control Mold and Mildew on Large, Inflatable, Non-Porous Plastic and Rubber Structures (animals, promotional items, moonwalk, slides, obstacle course play equipment, exercise equipment, and wrestling mats):** Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 8 ounces of this product (product name) per 4 gallons of water (2 ounces per gallon of water) (703 ppm active quaternary) (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not use equipment until treatment has been absorbed, set or dried.

**GENERAL CLEANING** – Apply (this product or product name) to soiled area with a mop, cloth, sponge, hand pump trigger sprayer or low pressure coarse sprayer. (This product or product name) can be diluted at 2 ounces per gallon or applied at full strength. Thoroughly wet soiled surface and scrub as necessary.

**DEODORIZATION** - To deodorize, apply (this product or product name) as indicated under the heading DISINFECTION.

#### **Cleaning/Deodorizing Directions:**

Add 1 to 2 ounces per gallon of water to clean and deodorize windows, mirrors and glass surfaces.

**Use a coarse spray device.** Spray 6-8 inches from surface, rub with sponge or cloth. Do not breathe spray mist.

## **POULTRY (AND SWINE) PREMISE DISINFECTION**

**Site Preparation:** The first step in any on-going sanitation program must be the removal of gross contamination and debris. This is accomplished by using a shovel, broom, or vacuum depending on the area to be disinfected. The efficacy of even the most efficient germicidal cleaner is reduced in the presence of heavy organic matter. Once the heavy debris is eliminated, thoroughly clean all surfaces with soap or detergent and rinse with water.

**Cleaning And Disinfection:** For all general cleaning and disinfection use 2 ounces of (this product or product name) per gallon of water. Apply (this product or product name) using a cloth, mop, hand pump trigger sprayer or low pressure coarse sprayer so as to thoroughly wet surface to be disinfected. Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution after each use.

## **APPLICATIONS AND USE DILUTION**

**Poultry (And Swine) Premise Disinfection (Special Instructions for Inactivating Avian Influenza A):** Remove all (poultry) (swine) (animals) and feeds from premises, trucks, cars, coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by (poultry) (swine) (animals). Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 2 ounces of (this product or product name) per gallon of water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house (poultry) (swine) (animals) or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. Immerse all halters, ropes, and other types of equipment used in handling and restraining (poultry) (swine) (animals), as well as forks, shovels, and scrapers used for removing litter and manure.

**Hatcheries:** Use 2 ounces of (this product or product name) per gallon of water to treat the following hard non-porous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more. Rinse with potable water before reuse. Then allow to air dry. For heavily soiled areas, a pre-cleaning step is required.

**Vehicles:** Clean all vehicles including mats, crates, cabs, and wheels with high pressure water and (this product or product name). Use 2 ounces per gallon to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes or more.

**Shoe Bath Directions:** Shoe baths containing one inch of freshly made solution must be placed at all entrances to buildings, hatcheries and at all the entrances to the production and packaging rooms. Scrape waterproof shoes and place in 2 ounces of (this product or product name) per gallon of water solution for 10 minutes prior to entering area. Change the use-solution in the bath daily or sooner if solution appears dirty.

**Dressing Plant Use:** Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution, 2 ounces of (this product or product name) per gallon of water. Scrub to loosen all soils. Allow to soak for 10 minutes and thoroughly rinse all wetted and cleaned surfaces with potable water.

**Veterinary Practice/Animal Care/Animal Laboratory/Zoos/Pet Shop/Kennels Disinfection Directions:** For cleaning and disinfecting the following hard non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 ounces of (this product or product name) per gallon of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

**Farm Premise Use:** Do not use in milking stalls, milking parlors or milk houses. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 2 ounces of (this product or product name) per gallon of water (or equivalent dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used in removing litter and manure. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

**Ultrasonic Bath Disinfectant Directions:** Use (this product or product name) to disinfect hard non-porous non-critical objects compatible with Ultrasonic cleaning units. Pour fresh solution at 2 ounces of (this product or product name) per

gallon of water directly into bath chamber. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Prepare fresh solution for each use.

**Disinfection of Hard Non-Porous Surfaces in Whirlpool Units:** After using the whirlpool unit, drain and refill with fresh water to just cover the intake valve. Add 2 ounces of (this product or product name) for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair, lift and any/all related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly cleaned, drain the solution from the unit and rinse any/all cleaned surfaces with fresh water. Repeat for heavy soiled units.

**Commercial Florist Use Directions:** To clean, disinfect and deodorize hard non-porous surfaces in one step, prepare use-solution by adding (mixing) 2 ounces per gallon of water. For heavy-duty use, add (mix) 8 ounces per gallon of water.

Remove all leaves, petals, garbage and refuse. Pre-clean surfaces using pressurized water where possible. Apply use-solution to hard (inanimate) non-porous surfaces thoroughly wetting surfaces as recommended and required, with a cloth, mop, brush, sponge or sprayer.

For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse mist pump or trigger sprayer. Spray 6-8 inches from surface; rub with brush, sponge or cloth. Do not breathe spray mist.

Treated surfaces must remain wet for 10 minutes. Allow to air dry.

Prepare a fresh solution at least daily or sooner if use-solution becomes visibly dirty.

**Disinfection of Barber/Salon Tools Directions:** Immerse pre-cleaned barber/salon tools (combs, brushes, razors, manicure/pedicure tools, clippers, scissors, trimmer blades) in a 2 ounces of this product (product name) per gallon of water use-solution (or equivalent dilution) (703 ppm active quaternary) for at least 10 minutes. Rinse instruments thoroughly and dry before reuse. A fresh use-solution must be prepared daily or more often if the use-solution becomes cloudy or soiled.

**NOTE:** Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean non-contaminated receptacle. Prolonged immersion may cause damage to stainless steel or metal instruments.

**Cleansing of Body Surfaces and Body Orifices of Human Remains:** To cleanse away skin secretions and accompanying malodor, to insure the removal of all soil and bloodstains, and to remove and reduce surface contamination, apply 8 ounces of this product (product name) to 4 gallons of water (2 ounces per gallon of water) (703 ppm active quaternary) (or equivalent dilution) to the surfaces and body openings, natural or artificial. Bathe the entire body using a sponge or washcloth. A soft brush may be employed on surfaces other than the face. Allow 10 minute contact time for optimal results. Prepare a fresh solution for application to each remains.

*(Not for use in California)*

#### **WATER AND SMOKE DAMAGE RESTORATION AGAINST ODOR-CAUSING BACTERIA AND FUNGI FOR INSTITUTIONAL, INDUSTRIAL AND HOSPITAL USE**

(This product or product name) is particularly suitable for use in water damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushion, sub floors, drywall, trim, and frame lumber, tackless strip and paneling. Mix 2 ounces of (this product or product name) per gallon of water, saturate affected materials with enough use-solution to remain wet for at least 10 minutes. Use proper ventilation.

**Sewer backup & river flooding:** During mitigation procedures, dilute 2 to 4 ounces of (this product or product name) per gallon of water allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil along with non-salvageable materials. Saturate all affected areas with a sprayer using a coarse spray tip, before and after cleaning and extraction.

**Carpets, carpet cushions and other porous materials such as sub floors, drywall, trim and frame lumber, tackless strip and paneling:** For water damage from a clean water source, extract excess water. Test hidden area for colorfastness. Mix 2 to 4 ounces of (this product or product name) per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil. Apply directly with a sprayer using a coarse spray tip, to fully saturate affected materials. Roll, brush or agitate into materials and allow the materials to remain damp for 10 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

**Special Instructions for Cleaning Carpet Against Odor Causing Bacteria:** (This product or product name) may be used in industrial and institutional areas: motels and hotels, nursing homes, schools and hospitals. For use on wet cleanable synthetic fibers, do not use on wool. Vacuum carpet thoroughly prior to cleaning. Test fabric for colorfastness.

**For portable extraction units:** Mix 2 ounces of (this product or product name) per gallon of water.

**For truck mounted extraction machines:** Mix 48 ounces of (this product or product name) per gallon of water and meter at 4 gallons per hour.

**For rotary floor machines:** Mix 4 ounces of (this product or product name) per gallon of water and apply at the rate of 300-500 sq. ft. per gallon.

Do not mix (this product or product name) with other cleaning products. Follow the cleaning procedures specified by the manufacturer of the cleaning equipment. After using this product, set the carpet pile and protect the carpet from furniture legs and bases while drying. Do not over wet. If applied to stain resistant nylon carpet, apply a fabric protector according to the carpet manufacturer's directions.

**(Not for use in California)**

**Carpet Deodorizer against Odor-Causing Bacteria for Institutional, Industrial and Hospital Use:** (This product or product name) deodorizes the carpet by controlling/reducing the growth of odor-causing bacteria. It can be used in industrial and institutional areas: motels, hotels chains, nursing homes and hospitals.

Vacuum carpet thoroughly prior to application. Mix 2 ounces of (this product or product name) per gallon of water. Follow the Injection and/or Extraction procedures as specified for any conventional steam cleaning equipment you are using. For rotary floor machines, mix 4 ounces per gallon of water and spray on carpet at a rate of 300-500 sq. ft. per gallon.

For use on washable synthetic fibers. Do not use on wool. Test colorfastness of carpet before use. Apply diluted product to a small concealed spot, then rub with a clean white cloth. If color changes or transfers to cloth, a water-based product should not be used.

After using the product, set carpet pile in one direction with a stiff brush. Place aluminum foil under the legs of furniture while carpet is drying. Over-wetting can cause carpet to shrink. Manufacturer assumes no responsibility for over-wetting misuse.

**Note:** This product should not be mixed with other cleaning products.

**Smoke Damage Restoration:** (This product or product name) is effective against odor causing bacteria and fungi in institutional, industrial and medical premises. (This product or product name) is particularly suitable for use in smoke damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushion, sub floors, drywall, trim and frame lumber, tackless strip and paneling. Follow directions as outlined in the Water Damage Restoration section. Using solutions recommended, saturate affected materials with enough product to remain wet for at least 10 minutes. Use proper ventilation.

*(Alternative language for bag in the box dispensing equipment)*

**Directions for Bag-In Box Containers:**

**HOW TO USE THIS PACKAGE:** This package is designed to be used with dilution control systems only. Open package and connect to dispenser according to directions on the box.

**TRIGGER SPRAYERS:** Fill bottle from dispenser. Apply to surfaces according to directions above.

**MOP BUCKETS:** Fill bucket from dispenser. Set up "Wet Floor" Signs. Mop floor surfaces as specified in directions above.

*(Alternate language)*

**DILUTION SYSTEM SPECIFIC DIRECTIONS FOR USE**

**(Automatic Dilution)(Dilution System Name) ((Closed)(Open) Loop):** (Concentrated product – dilute before using)

ATTACH this product (PRODUCT NAME) TO THE AUTOMATIC DILUTION CENTER: Remove white cap from product bottle. DO NOT REMOVE purple PLUG FROM BOTTLE THROAT! Attach the bottle to the automatic dilution center by screwing on matching purple dispensing cap connected to dilution center. Push down while screwing on cap. This dispensing system delivers 2 oz. per gallon of water (2:128) (1:64) use solution.

**(OR)**

**<<System Descriptors:>>**

(The) ProFill (Dispensing) (Unit) (System)

(The) EZFill (Dispensing) (Unit) (System)

(The) Dilute2Go (Dispensing) (Unit) (System) (D2G)

(The) (MDU) (MDD) (Mobile) (Dispensing) (Dilution) (Device) (Unit) (System)

(The) (PDU) (PDD) (Portable) (Dispensing) (Dilution) (Device) (Unit) (System)

**<<Optional Text:>>**

(Simple.) (Smart.) (Clever.) (Designed to Dilute.) (Ready-to-Dilute.) (Accurate.) (Reduce product overuse (waste).)

(Effective.) (No chemical contact (with concentrate).) (No risk of product cross contamination.) ( Easy operation.)

(Minimal training.) (Durable (during)(use)(transport).) (Effective.) (Sealed bottle.) (Dilution control.) (Portable (concentrate) (dilution).) (Plug and Go.) (Connect and Go.)

({insert appropriate number}) (gpm) (gallons per minute) (flow) (fill) (rate).

(Dilution ratio based on product used.)

(This dispensing system delivers 2 oz. (product) per gallon of water (2:128) (1:64) use solution.)

(!TURN OFF water supply after use and disconnect.)



**<<Optional Text:>>**

**TO FILL SPRAYERS (BUCKETS):**

1. Attach (system descriptor) (unit) to water source (using (water) (hose) (and) (or) (quick-connect) (provided))).  
(Turn on water supply (to pressurize unit).)
2. Pull back (small) (green)({other color}) locking tab from {(off) (representative "off" icon)} notch (with thumb).
3. While holding back tab, use opposite hand to slide (yellow) ({other color}) selector bar to {(spray bottle) (bucket) (representative spray bottle icon) (representative bucket icon)) (position) to dispense product. (The {(faucet)(representative faucet icon)) (position) dispenses water only (for rinsing)).
4. {Note to reviewer: One or both of the following statements will be used}  
(For spray bottle(s) (applications):) Insert spray bottle under (dispenser) nozzle.  
<<and/or>>  
(For bucket(s) (applications):) {(Hold) (Hang)} (dispenser) nozzle (over bucket) (on bucket rim).
5. Push down (red) ({other color}) trigger (to fill spray bottle) (to fill bucket) (for product flow) (into a bottle) (into other container). (Release (red) ({other color}) (trigger) to stop.)
6. (See (service) (instruction) manual (insert) for (more) (detailed) (usage) information.)

**TO TRANSPORT:**

1. (Pull back (small) (green) ({other color}) locking tab and) slide (yellow) ({other color}) selector bar to {(faucet) (representative faucet icon)) (position). (Unit now dispenses water only (and can be used for rinsing) (by pushing down (red) (other color) trigger).)
2. Turn off water (at the source).
3. (While still in the {(faucet) (representative faucet icon)) (position),) push down (red) ({other color}) trigger to release water pressure. (A small amount of water will be discharged.) (Pressure will be released from the unit.)
4. (Once pressure is released (from the unit),) (pull back (small) (green) ({other color}) locking tab and) slide (yellow) ({other color}) selector bar to {(off) (representative "off" icon)) (position). (Disconnect water hose from unit.) ((Unit) (System Descriptor) is now ready for transport.)

**(OR)**

**Automated Dilution System (Dilution System Name):** Remove cap/spray nozzle from empty container. Fill empty container with a newly prepared use-solution. Replace cap/spray nozzle. Place correct use-dilution label on newly filled container.

**(OR)**

**Smart Mix Pro Dispensing System:**

1. Fill Smart Mix Pro pouch with cold water to the fill line arrow below the cap.
2. Fold and Squeeze the chemical concentrate to burst inner pouch.
3. Shake the bag to mix chemical fully.
4. Use the push button to fill the bottle.

Once water and concentrate are mixed, 1 gallon (3.8 Liters) of ready to use (disinfecting/cleaning) (disinfecting) solution.

**(OR)**

**Integrated Dispensing System (Name of Integrated Dispensing System) (Control Knob Key)** - Attach to source of potable water with quick connect attachment.



Rotate control knob to (2:128)( ) for low flow rate applications such as filling trigger spray bottle.

**(1:64)**



Rotate control knob to (2:128)( ) for high flow rate applications as filling a mop bucket.

**(1:64)**

Squeeze handle to dispense a 2 oz. per gallon of water (1:64 or 2: 128) use solution of product.

**(OR)**

**PACKETS** - *Pre-measured tear open packets* – (Simply) (tear) (open and) pour contents (of packet) into x gallons of

water (for a 1:64 (or) 2: 128) dilution). Keep packets in box until ready to use. (Pour contents of packet into x gallons of water for a 1:64 (2: 128) dilution.)

or

Pour contents of (1 or 2 oz)(xoz) packet into (1 or 2)(x) gallons of water. Keep packets in box until ready to use.

**(OR)**

**INTERMEDIATE SERVICE SOLUTION CONTAINER:**

1. Create Intermediate Service Solution by combining (x oz product) (x packet(s)) and x (oz) (gal) water for a (x:x) intermediate dilution.
2. Combine x (oz) of the Intermediate Service Solution and x (oz)(gal) water to achieve the final use dilution of 2:128 or 1: 64.
3. Follow Directions for Use for, (Disinfection), (Insert applicable use header).

**Alternate instruction for product used in conjunction with applicator/sprayer name:**

To Connect with insert applicator/sprayer name

Follow the proper (step)(calculation) to achieve the final use dilution of 1: 64 or 2: 128.

[Connect]

Connect adaptor cap [from insert applicator/sprayer name] [to bottle] and twist until tight[ened]. [Refer to user manual for specific operating instructions before use]

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

*(Required for products supplied in containers 5 gallons or greater.)*

### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Contains no phosphorous.

## **STORAGE AND DISPOSAL**

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**PESTICIDE STORAGE** - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

*(for products with household/residential use-sites only)*

**CONTAINER DISPOSAL** – Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

*(for products with industrial, institutional and commercial use sites))*

**CONTAINER DISPOSAL** – Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Triple rinse container promptly after emptying.

*(Containers 5 gallons or less)*

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

**Note to reviewer:** The following one-way opening container qualifier is optional language and not required on the in-commerce label.

*(For products with industrial, institutional and commercial use sites and containers with a one-way opening for use in automatic dilution/dispensing systems:)*

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. When container is empty, replace cap and discard in trash.

*(Containers greater than 5 gallons):*

Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

*(Reusable Container Statement)*

A container, such as a spray bottle, can be reused once empty. First prepare an appropriate use-solution from concentrate. A dilution dispenser (or name specific equipment such as the Dynamix dispenser) can be used to prepare the use-solution. Remove cap/spray nozzle from empty container. Fill empty container with a newly prepared use-solution. Replace cap/spray nozzle. Place correct use dilution label on the newly filled container.

**PACKET DISPOSAL** - Do not reuse; discard empty container and put in trash.

**PESTICIDE DISPOSAL** - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

## **GRAPHICS**

*(Note to Reviewer: These are representative icons for use sites/application methods that may appear on the label listed in the location/surfaces section of this label with the appropriate directions for use, PPE or package type.)*

(intermediate service solution container)  
(spray dispensing container)  
(sprayer system)  
(sink with faucet)  
(work station tub or sink)  
(rubber gloves) (masks)(PPEs)  
(table)  
(chair)  
(bed frame)  
(wall)  
(cabinet)  
(doorknob)  
(garbage can)  
(non-wooden picnic table)  
(outdoor furniture except cushions and wood frames).  
(Telephone)  
(non-food contact counter tops, equipment, shelves, racks and carts)  
(shower stalls)  
(shower doors and curtains)  
(tubs)  
(glazed tiles)  
(toilets)  
(urinals)  
(glazed porcelain tile) and (restroom fixtures).

2 OUNCE PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL:

MIX EACH PACKET WITH 1 GALLON OF WATER

## NP 4.5 (D&F) DETERGENT/DISINFECTANT

EPA Reg. No. 1839-95

EPA Est. No. 1839-IL-1

NET CONTENTS: (2) FLUID OZ.

### ACTIVE INGREDIENTS:

Alkyl (60% C<sub>14</sub>, 30% C<sub>16</sub>, 5% C<sub>12</sub>, 5% C<sub>18</sub>)

dimethyl benzyl ammonium chlorides ..... 2.25%

Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>)

dimethyl ethylbenzyl ammonium chlorides ..... 2.25%

**INERT INGREDIENTS** ..... 95.50%

**TOTAL** ..... 100.00%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

SEE OUTER CONTAINER FOR PRECAUTIONARY STATEMENTS AND USE DIRECTIONS

**DISPOSAL:** Do not reuse container. Wrap and put in trash collection.

### STEPAN COMPANY

22 W. Frontage Rd.

Northfield, IL 60093

## **SECONDARY / SERVICE CONTAINER LABELING**

*(Note to Reviewer: The following is to be used as a label for a separate, secondary container for use/storage of a 1:64 use solution (or equivalent dilution). Not for use with alternate dilutions)*

*When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements:*

### **NP 4.5 (D&F) Detergent/Disinfectant/ Product Brand Name**

E.P.A. Reg. No. 1839-95  
E.P.A. Est. No. 1839-IL-1 (xxx-xx-xxx)

#### **ACTIVE INGREDIENTS**

Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chlorides .....	2.25%
Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> )	
dimethyl ethylbenzyl ammonium chlorides.....	2.25%
<b>(INERT)(OTHER) INGREDIENTS .....</b>	<b>95.50%</b>
Total.....	100.00%

*The product in this container is diluted as directed on the pesticide product label. Follow the directions for use on the pesticide label when applying this product. Further sale or distribution of this product is strictly prohibited.*

**KEEP OUT OF REACH OF CHILDREN**

### **PRECAUTIONARY STATEMENTS**

**KEEP OUT OF REACH OF CHILDREN.** Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

STEPAN COMPANY  
22 W. Frontage Rd.  
Northfield, IL 60093